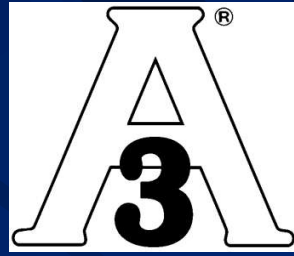


**U.S. Food and Drug Administration  
Public Workshop  
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June 8-9, 2011**

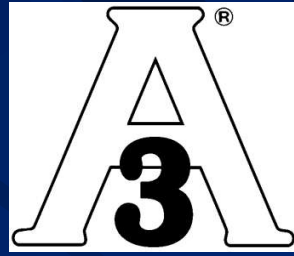
**3-A Sanitary Standards, Inc.  
Designing for Cleanability  
Lessons from the Food Industry**





# Topics

- **Introduction and Overview: 3-A SSI**
- **The Role and Value of 3-A Sanitary Standards**
- **Design Criteria for 3-A Sanitary Standards**
- **Oversight of Conformance to 3-A Sanitary Standards**



## **The Origin of 3-A Sanitary Standards**

- **1920s: Dairying and milk distribution**
- **Regulatory world characterized by conflicting jurisdictional requirements**
- **International Association of Dairy and Milk Inspectors formed Committee on Dairy and Milk Plant Equipment**
- **Purpose: “...to confer with manufacturers and gradually develop standards which would generally be accepted.”**



## **The Origin of 3-A Sanitary Standards**

- **First standard developed in 1929 for sanitary fittings**
- **Work slowly broadened throughout the 1930s**
- **After WW II, stakeholders gained momentum in formulating and publishing standards formally identified as '3-A'**



## **Brief History of 3-A SSI**

**1920**  
**First Standard**

**1944 USPH**  
**Participation**

**1956**  
**New Symbol**

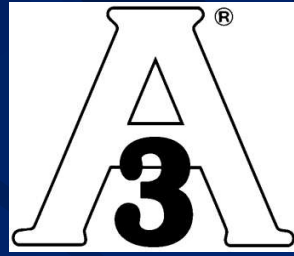
**2002**  
**3A-SSI**

# The 3-A SSI Stakeholders

- Regulatory Sanitarians
- Processors (Users)
- Fabricators

3-A Sanitary Standards, Inc.





## **3A Sanitary Standards, Inc. Today**

- **Not-for-profit corporation: 501 (c) (3)**
- **Governed by Board of Directors representing the three stakeholder groups with a long history of collaboration on sanitary equipment design**
- **Dedicated, independent staff**

# What is a 3-A Sanitary Standard?

3-A Sanitary Standards specify the criteria for the design and fabrication of equipment that comes into contact with food.





# 3-A Sanitary Standards

- Vessels
- Fillers
- Valves and Fittings
- Pumps and Mixers
- Heat Exchangers
- Conveyors and Feeders
- Instruments
- Concentrating Equipment
- Farm/Raw Milk
- Cheese and Butter Equipment
- Materials and Materials Testing







# The Role of '3-A' in Commerce

## USPHS/FDA Pasteurized Milk Ordinance (PMO)

Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this *Ordinance*.

# The Role of '3-A' in Commerce

USDA – General Specifications for Dairy  
Plants Approved for USDA Inspection  
and Grading Service

All new, replacement or modified equipment and all processing systems, cleaning systems, utensils, or replacement parts shall comply with the most current, appropriate 3-A Sanitary Standards or 3-A Accepted Practices.

# 3-A Value: Regulatory Sanitarians

- 3-A Sanitary Standards embody decades of expert knowledge about equipment design from inspection authorities and others.
- 3-A Sanitary Standards streamline the equipment inspection process and help ensure the safety of food.
- The 3-A Symbol signifies equipment is compatible with regulatory requirements and guidelines.



## 3-A Value: Processors and Fabricators

- The 3-A Sanitary Standards and 3-A Accepted Practices are written to conform to regulatory requirements and guidelines.
- Buyers and sellers rely on 3-A because it signifies equipment that's easier to clean, inspect, and maintain.

# Key Elements of 3-A Sanitary Standards and Accepted Practices

- Definitions of Terms Used
- Description of Permitted Materials
- Details of Fabrication

# Format and Style Manual

- Document Preparation Guide for Document Writers
- Explains the Intent of Each Section of the Document
- Standardization of:
  - Abbreviations
  - Dual Dimensioning (Inch-Pound followed by Metric)
  - Rules for Conversion between I-P and Metric
  - Number of Significant Digits
- Boilerplate Wording

# Available at: [www.3-a.org](http://www.3-a.org)

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# Definitions

- For consistent and uniform interpretation and application of standards.
- To define special or unusual terms used in the document.
- Definitions not used in the document should not be included.
- As appropriate, new definitions can be created.



# Definitions

## Examples and Notes for Drafters

- Properties of Design
- Cleaning
- Fittings



*Bond:* The adhesive or cohesive forces holding materials together. This definition excludes press and shrink fits.

*Mechanical Force Seal:* The seal established between a flexible rubber, rubber-like, or plastic material when pressed into a special groove in a metal or glass component using a combination of compression, pressure, and the unique geometrical shapes of the joined materials to create a tight seal at the interface of the materials joined during conditions of intended use including processing, cleaning, sanitizing, or sterilization. A mechanical force seal is not intended for routine disassembly for cleaning.

*Clean-in-Place Cleaning:* (CIP): The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned. Components of the equipment, which are not designed to be cleaned in place, are removed from the equipment to be COP or manually cleaned.

**Drafters Note:** Insert one of the following statements as the last sentence of C3.1.

**Product contact surfaces to be CIP cleaned are inspectable.**

**(or)**

**Product contact surfaces to be CIP are inspectable except as specified in E1.5.2.2**

Other methods of cleaning are also defined:

*Clean-Out-of Place (COP)*

*Manual Cleaning*

*Dry Cleaning*

Other Key Terminology defined:

*Cleanable or Cleanability*

*CIPable*

*Close Coupled*

*Readily Accessible:* A location that can be safely reached by personnel from the floor, other permanent work area or stable platform (permanent or moveable).

*Readily Removable:* Designed, fabricated, and installed to be quickly separated from the equipment with or without the use of simple hand tools.

*Simple Hand Tools:* A screwdriver, wrench, mallet, or readily available dedicated tool(s) normally used by operating and cleaning personnel.

*Product Contact Surfaces:* All surfaces which are exposed to the product and surfaces from which splashed product, liquids or material may drain, drop, diffuse **{Where Applicable}**, or be drawn into the product or onto product contact surfaces. **{Surfaces That Come Into Contact With Product Contact Surfaces Of Packaging Materials May Be Included In This Definition For Some Equipment.}**

*Nonproduct Contact Surfaces:* All exposed surfaces from which splashed product, liquids, or other materials cannot drain, drop, diffuse **{Where Applicable}** or be drawn into or onto the product, product contact surfaces, open packages, or the product contact surfaces of package components.

## Fittings Definitions:

*CIP Fittings* – Fittings to be cleaned while fully assembled. If such a fitting has a removable joint, the joint is self-centering, employs a gasket, and the resulting gasketed joint forms a substantially flush interior surface.

*Manually Cleaned Fittings* – Removable joint fittings of which the design requires dismantling for manual cleaning.



# Materials

- To identify what materials can be used to fabricate the equipment.
- Product Contact Surfaces
  - Metals
  - Nonmetals
- Nonproduct Contact Surfaces

Product contact surfaces shall be of stainless steel of the American Iron and Steel Institute (AIST) 300 Series, excluding 301, 302, and 303, (Refer to B4, Reference No. 5) or corresponding Alloy Cast Institute (ACI) types (Refer to B4, Reference No. 6) or metal which under conditions of intended use is at least as corrosion resistant as 304 stainless steel, and is nontoxic and nonabsorbent. (Refer to Appendix, Section H.) Where welding is involved, the carbon content of the stainless steel shall not exceed 0.08%.

Rubber and rubber-like materials may be used for **{All Required Application(s) Including Coatings}** and when used for the specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 18-.

Plastic materials may be used for **{All Required Application(s) Including Coatings}** and when used for the above-specified application(s), shall conform to the applicable provisions of 3-A Sanitary Standard, Number 20-.

Carbon and ceramic materials (including tungsten carbide) may be used for **{List Applications}** and when used, shall be inert, nonporous, nontoxic, nonabsorbent, insoluble, resistant to scratching, scoring, and distortion when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitizing treatment **(or sterilization)**. **{If the Optional Parenthetical Words are Used, Refer to D1.3 and E1.16.}**

All nonproduct contact surfaces shall be of corrosion-resistant material or material that is rendered corrosion resistant. If the surfaces are coated, including painted surfaces, the coating shall adhere. All nonproduct contact surfaces shall be relatively nonabsorbent, durable, and cleanable. Parts removable for cleaning having both product contact and nonproduct contact surfaces shall not be painted.

# Fabrication

- Equipment is to be designed to be 100% cleanable.
- The design must preclude contamination of the product.
- Fabrication to 3-A criteria DOES NOT automatically imply compatibility with CIP cleaning methods.
- Illustrations are not to be interpreted as engineering drawings.

# Product Contact Surfaces

Surfaces, including fabricated, welded and soldered joints, shall be at least as smooth as a 32 min. (0.8 mm)  $R_a$  finish and shall be free of pits, folds, crevices, and cracks in the final fabricated form. (Refer to Appendix, Section I.), except that;

Sanitary tubing joints, welded in accordance with E1.2.2, and free of pits, folds, crevices, and cracks, and misalignments, may have an as-welded **interior** surface finish.

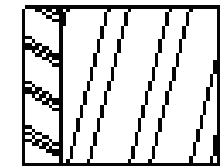
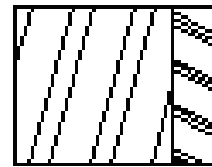
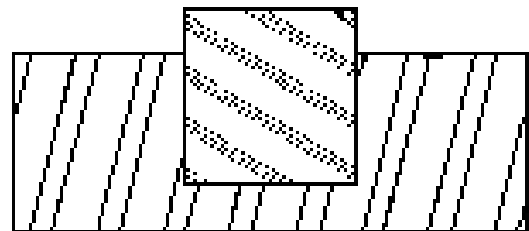
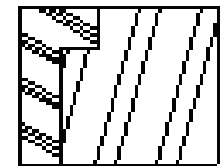
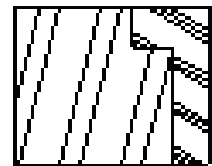
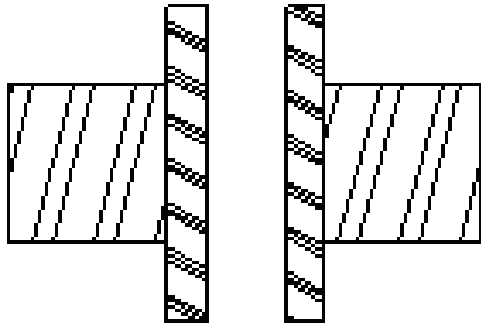


All permanent joints in metallic surfaces shall be continuously welded, except that:

Press-fits, force-fits, or shrink-fits may be used to produce crevice-free permanent joints only when neither welding nor soldering is practical. Joints of these types may only be used to assemble metallic parts having circular cross sections, free of shoulders or relieved areas. Press-fitting, force-fitting, or shrink-fitting may be used for **{List all Application(s)}**. (Refer to B4, Reference No.15.) (See the following illustrations of acceptable press-fits, force-fits, or shrink-fits.)

If press-fit or shrink-fit procedures are to be used for metal to plastic or plastic to plastic joints, supporting documentation shall be available to demonstrate the joints suitability. The tightness of the press-fit or shrink-fit seal shall be validated to demonstrate that there is no migration past the seal under the intended conditions of use. This shall be accomplished using the EHEDG Document No. 7, Test for Bacterial Tightness or other equally effective test(s).





A mechanical force seal may be used for **{List all Application(s)}**. The tightness of the seal shall be validated to demonstrate that there is no migration past the seal. The interior of the gasket groove shall be designed so the groove is inspectable and cleanable when the gasket is removed.

The manufacturer shall provide a field replacement procedure for the mechanical force seal that has been validated to the original installation tightness to prevent liquid penetration past the seal.

The surfaces behind mechanical force seals shall be easily cleanable and inspectable or the impermeability of the seal shall be established by an appropriate test.

Rubber and rubber-like materials, and plastic materials, and carbon or ceramic seal component materials may be bonded. The bond shall be continuous and mechanically sound. The rubber and rubber-like material, the plastic material, and carbon or ceramic seal component materials shall not separate from the base material to which it is bonded when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitizing treatment **(or sterilization)**.  
**{If the Optional Parenthetical Words are Used, Refer to D1.3 and E1.16.}**

Coatings, when used, shall be free of delamination, pitting, flaking, spalling, blistering, or distortion when exposed to the conditions encountered in the environment of intended use, including cleaning and sanitizing treatment **(or sterilization)**.  
**{If the Optional Parenthetical Words are Used, Refer to D1.3 and E1.16.}**

## Cleaning and Inspectability

Equipment intended for COP or manual cleaning shall be designed and fabricated so all product contact surfaces are readily accessible and inspectable either when in an installed position or when removed. Junctures between components may or may not be gasketed or sealed. All demountable appurtenances shall be readily removable.

Equipment intended for CIP cleaning shall be designed and fabricated so all product contact surfaces, including all non-removed appurtenance, can be CIP cleaned. Junctures between components shall be sealed or designed for manual or COP cleaning.

Surfaces shall be self-draining except for typical clingage or adherence.

Surfaces shall be drainable and provided with sufficient drain points so the equipment can be drained.

When components are close coupled, the intervening product contact surfaces shall be the lesser of:

1. Twice the nominal diameter or cross section of the mating surfaces, or
2. A maximum of 5.0 in. (127 mm) as measured from the outer shell of the vessel to the point at which product is stopped by a valve seat or fitting cap.



The fitting for a temperature-sensing device intended for sensing processing or holding temperature in a vessel shall be located no higher than the 20% capacity level of the vessel.

Gaskets shall be removable or bonded.

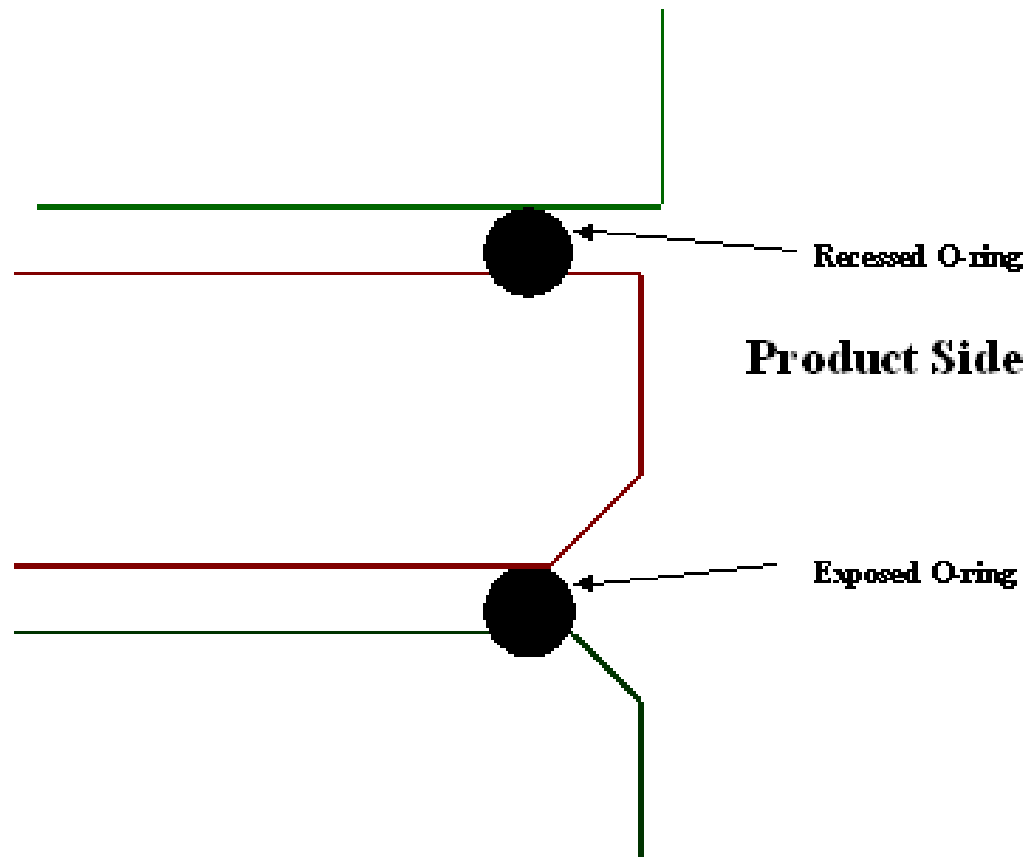
Gasket retaining grooves for removable gaskets shall not exceed 1/4 in. (6.35 mm) in depth or be less than 1/4 in. (6.35 mm) wide except those for O-rings with cross-section dimensions 1/4 in. (6.35 mm) or smaller, and those provided for in the 3-A Sanitary Standards referenced in Section B, Normative References (except that:)

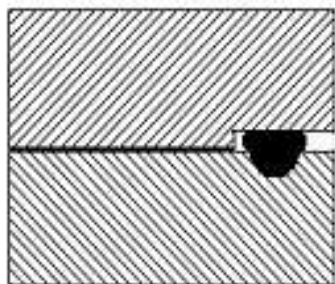
Gaskets between flat sealing surfaces shall be substantially flush with the product contact surfaces. The juncture shall create a crevice free joint, without any unsupported gasket material.

Surfaces with two or more O-rings or seals in a row between product contact and nonproduct contact surfaces shall have a leak-detection port between them that is open to the atmosphere and visible to the operator, unless this area is designed for manual or COP cleaning. The leak-detection port shall be a minimum of 1/8 in. (3.18 mm) in diameter.

Gasketed joints employing recessed O-rings or seals which are intended for CIP shall be substantially flush so that some of the O-ring or seal surface will be partially exposed to cleaning solutions (See following illustrations of examples)

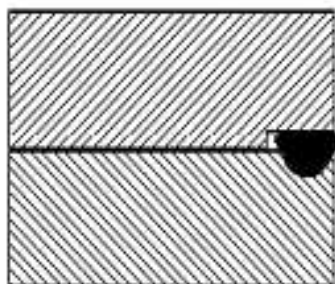
The surfaces behind removable gaskets under compression shall be easily cleanable and inspectable.





**HARD TO CLEAN RECESSED SEAL LOCATION**

**(NOT ACCEPTABLE FOR CIP CLEANING. MUST  
BE DISASSEMBLED FOR CLEANING)**



**EASY TO CLEAN BY C.I.P.**

**( SEAL LOCATED AND COMPRESSED TO FIT FLUSH  
OR WITH SLIGHT BULGE )**

All angles of less than  $135^\circ$  shall have radii of at least **{Provide suitable numbers, 1/4 in. (6.35 mm) or 1/8 in. (3.18 mm)}**, except that:

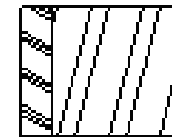
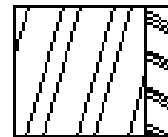
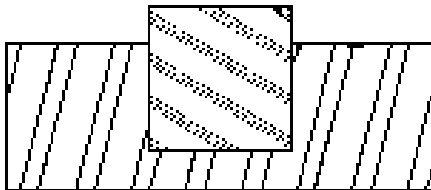
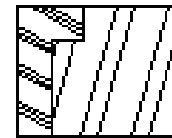
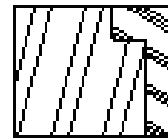
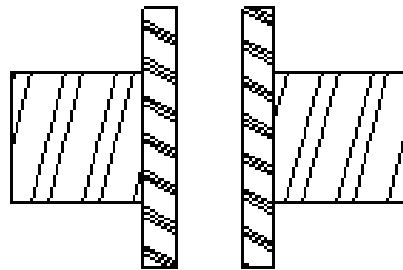
Allowance for smaller radii down to 1/32 in.

Grooves in gaskets and gasket retaining grooves.

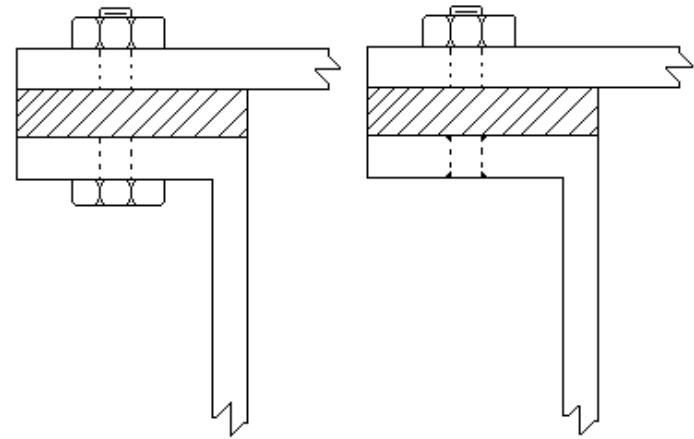
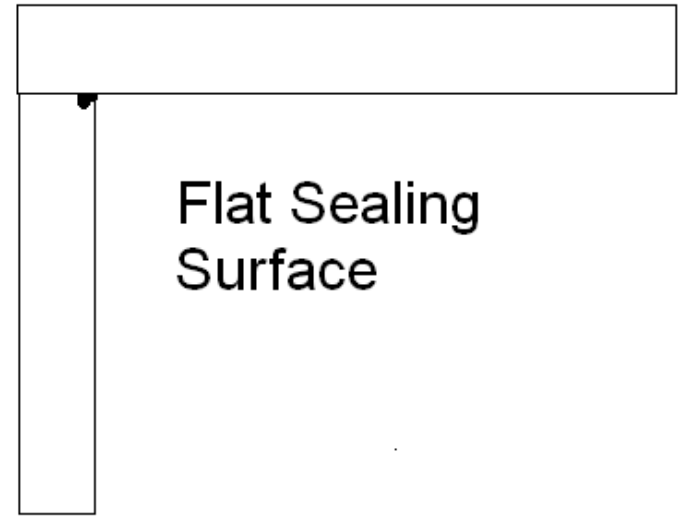
Smaller radii for standard and nonstandard O-ring grooves



There are no minimum radii requirements for soldered joints or for the product contact junctures of press or shrink fits.



There are no minimum radii requirements for the product contact junctures of flat sealing surfaces.

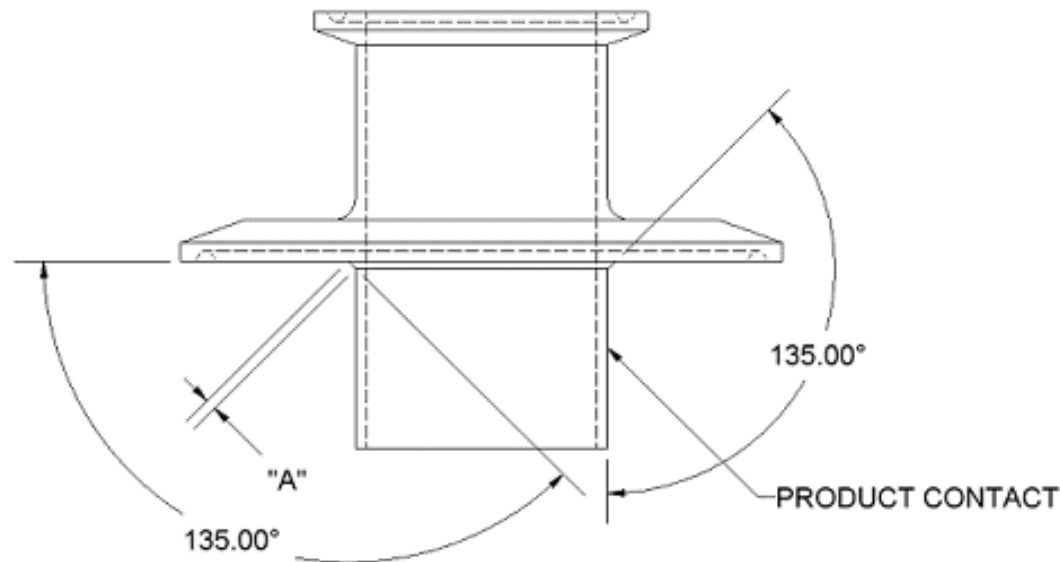


There are no minimum radii requirements for exposed sanitary threads except for the knuckle thread, DIN 405, provided for by Section E1.13.1.1.

Gasket retaining grooves for bonded gaskets are not subject to width, depth, or minimum radii requirements.

There are no minimum radius requirements for retaining grooves for mechanical force seals defined in C1.1, or for the juncture between product contact surfaces and the exposed part of an O-ring.

In such case on a machined component when a radius in a  $90^\circ$  corner is replaced with a pair of  $135^\circ$  angles, the distance between the corners (the hypotenuse of the resulting isosceles right triangle) shall be no less than  $1/32$  in. (0.794 mm) inches for the dimension "A" in the illustration below.



MACHINED FROM ONE PIECE OF METAL

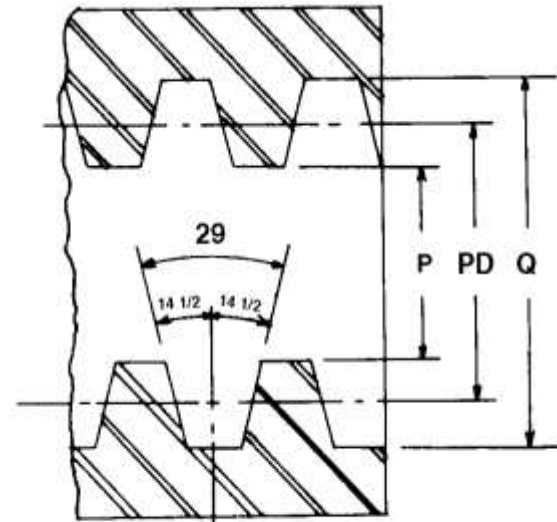
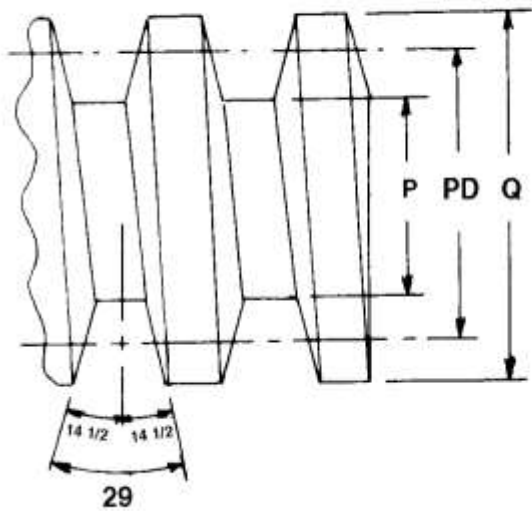
There shall be no exposed or enclosed threads on product contact surfaces.

Or

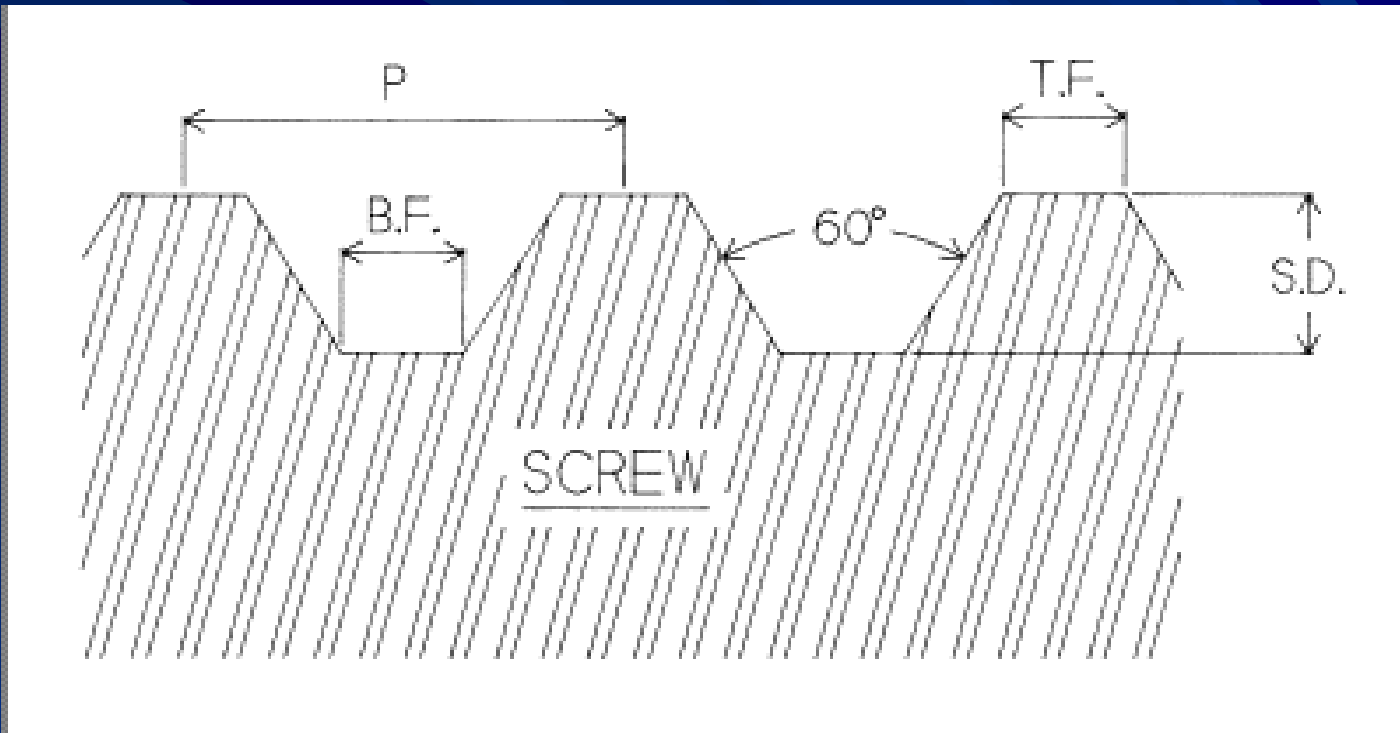
Use of threads is not recommended and threads should not be used when other means of attachment is available. When no acceptable alternative is available and threads are required for essential functional reasons, the following criteria shall apply:



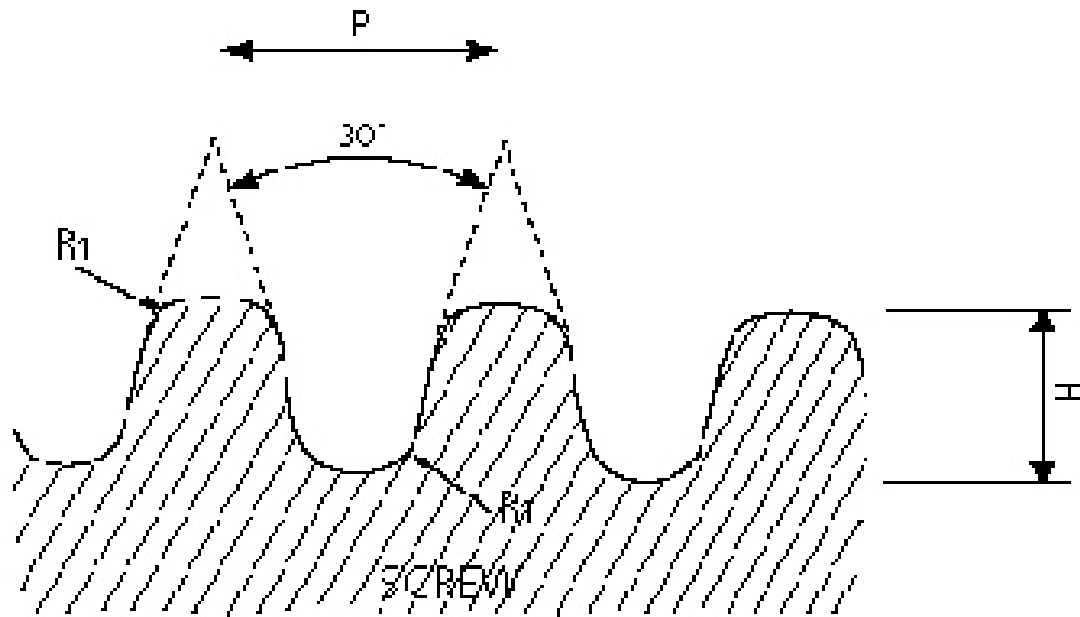
# ACME Thread



# American Standard Stub Acme Thread



# Knuckle Thread DIN405



$P$  = Pitch

$H$  = Depth of thread

$R_1$  = Radius

$$H = 0.5 \times P$$

$$R_1 = 0.24 \times P$$

# Nonproduct Contact

- Surfaces
- Joints
- Coatings
- Cleanability and inspectability
- Draining
- Exposed threads
- Service Lines

- Panels, Doors, or Access Ports
- Guards and safety Devices
- Supports
- Catwalks, stairs handrails
- Name and Information Plates



# Oversight of Conformance

- The 3-A Symbol is a registered mark to be used to show conformance to a 3-A Sanitary Standard.
- 3-A SSI was created to implement a new Third Party Verification (TPV) inspection program for all users of the mark.



# Why a New TPV Requirement?

- TPV brings added assurance that equipment showing the 3-A symbol fully conforms to the applicable 3-A Sanitary Standard.



# More Details on 3-A SSI

- Contact us at:

6888 Elm Street, Suite 2D

McLean, Virginia, 22101

PH: 703-790-0295

FAX: 703-761-6284

- Contact Timothy Rugh or Nate Wall

[Trugh@3-a.org](mailto:Trugh@3-a.org) or [nwall@3-a.org](mailto:nwall@3-a.org)

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# Consensus Process - Overview

